

OCT 13 1998

K982871

DADE BEHRING

DADE BEHRING INC.
P.O. Box 6101
Newark, DE 19714

Summary of Safety and Effectiveness Information

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter's Name: Rebecca S. Ayash
Dade Behring Inc.
Building 500, Mailbox 514
P.O. Box 6101
Newark, DE 19714-6101

Date of Preparation: 8/13/98

Device Name: Drug Calibrator II

Classification Name: Calibrator, Drug Mixture

Predicate Device: Drug Calibrator II (K962817)

Device Description: Drug Calibrator II (K962817) is being modified to add valproic acid as an additional constituent on the product labeling. Drug Calibrator II is a liquid product. Level 1 is bovine albumin. Levels 2 through 5 contain acetaminophen, carbamazepine, gentamicin, tobramycin, valproic acid and vancomycin in a bovine albumin base. The kit consists of ten vials; two at each of five levels, containing 5 mL each.

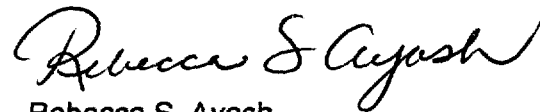
Intended Use: Drug Calibrator II is intended to be used to calibrate the Acetaminophen (ACTM), Carbamazepine (CRBM), Gentamicin (GENT), Tobramycin (TOBR), Valproic Acid (VALP), and Vancomycin (VANC) methods for the Dimension® clinical chemistry system.

Comparison to Predicate Device:

	Drug Calibrator II	Drug Calibrator II (Modified)
Intended Use	Calibrator	Calibrator
Analyte	Acetaminophen, carbamazepine, gentamicin, tobramycin, vancomycin	Acetaminophen, carbamazepine, gentamicin, tobramycin, valproic acid, vancomycin
Matrix	Bovine albumin	Bovine albumin
Form	Liquid	Liquid
Volume	5.0 mL per vial	5.0 mL per vial
Levels	5 levels	5 levels

Comments on Substantial Equivalence: Drug Calibrator II (modified) is the same product as the product currently marketed (K962817) with the only difference being revision of the labeling to add the constituent valproic acid. Both products are intended to be used as calibrators for drug assays.

Conclusion: Drug Calibrator II (modified) is substantially equivalent to the currently marketed Drug Calibrator II based on the comparison summarized above.

A handwritten signature in black ink, reading "Rebecca S. Ayash". The signature is fluid and cursive, with the first name "Rebecca" being more prominent and the last name "Ayash" following in a similar style.

Rebecca S. Ayash
Regulatory Affairs and
Compliance Manager
Date: 8/13/98



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 13 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Rebecca S. Ayash
Regulatory Affairs and Compliance Manager
Dade Behring, Inc.
Glasgow Building 500, Mailbox 514
P.O. Box 6101
Newark, Delaware 19714-6101

Re: K982871
Drug Calibrator II
Regulatory Class: II
Product Code: DKB
Dated: August 13, 1998
Received: August 14, 1998

Dear Ms. Ayash:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

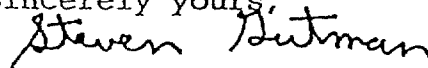
Page 2

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



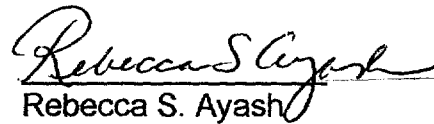
Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications Statement

Device Name: Drug Calibrator II

Indications for Use: Drug Calibrator II is an *in vitro* diagnostic product intended for use in an *in vitro* test system to establish points of reference that are used in the determination of values in the measurement of human substances.



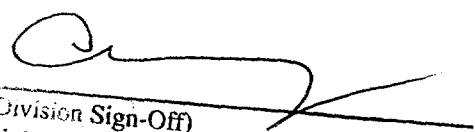
Rebecca S. Ayash
Regulatory Affairs and
Compliance Manager
Date: 8/13/98

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)_____

510(k) Number

Division Sign-Off
Office of Device Evaluation



(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number 6982871